

PETITION under 37 C.F.R. 1.181	Attorney Docket No.	KINE-001CIP5
	Confirmation No.	5685
	First Named Inventor	DEDHAR, SHOUKAT
	Application Number	09/998,250
	Filing Date	November 30, 2001
	Group Art Unit	1617
	Examiner Name	WILLIAMS, LEONARD M.
	Title: <i>"TREATMENT OF INFLAMMATORY DISEASES INCLUDING PSORIASIS"</i>	

Commissioner for Patents
P.O. Box 1450
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Sir:

Applicants respectfully request the Commissioner to review the restriction requirement in the above-captioned patent application.

As originally filed, the present application contained Claims 1 – 14. In the Office Communication of February 24, 2003, Claims 1 – 14 were subjected to a restriction, in which the claims were divided into four groups; Group I being drawn to a method for treating inflammation by administering an antisense molecule; Group II being drawn to a method for treating inflammation by administering an antibody; Group III being drawn to a method for treating inflammation by administering a small molecule; and Group IV being drawn to a method for treating inflammation by administering an agent that modulates PtdIns (3, 4, 5)P3 levels. The basis for the restriction was stated to be as follows:

Groups I-IV are distinct from each other because they are drawn to materially different methods using compositions having different chemical structure, physical properties and biological functions, and requiring separate search: antisense nucleic acids, antibodies, small organic molecules that blocks ILK catalytic or binding activity and agents that affects ILK activity through direct or indirect modulation of PtdIns(3, 4, 5)P3 levels. Those methods differ at least in method steps, reagents and doses used, schedules used, response variables, and criteria of success. They have different classifications and the search would not be coextensive. Thus, groups I-IV are patentably distinct from each other.

In response to the restriction requirement, the Applicants elected Group III for examination, in accordance with 37 C.F.R. 1.144; amended Claim 1 to recite the administration of a small molecule; cancelled Claims 11 and 12; and traversed the restriction requirement.

On June 4, 2003 the Office improperly indicated that the Applicants' election was without traverse, but noted the request for rejoined of Group IV and asserted that the issue would be addressed after allowance of the claims. Consequently, Claims 11, 12 and 14 were withdrawn from consideration. On September 8, 2004, Claims 2-12 and 14 were cancelled and on November 4, 2005, Claim 13 was cancelled.

On November 4, 2005, Claims 15 – 22 were introduced. Claim 1 is directed to a method for treating psoriasis, Claims 15 – 17 are dependent upon Claim 1, and recite the additional step of co-administering a secondary therapy for psoriasis, Claims 18 – 19 are dependent upon Claim 1, and are directed to a mode of administration of the ILK inhibitor of Claim 1, Claim 20 is directed to a method of treating psoriasis that includes the step of staining.

Claims 15 – 22 were subjected to a restriction in the Office Communication of February 6, 2006, in which Claims 15 – 22 were withdrawn from consideration. The communication further stated that the basis for the restriction was as follows:

"New claims 15 – 22 have been added, but are not addressed due to original presentation."

On August 1, 2006, the Applicants traversed this restriction requirement with respect to Claims 15 – 20 and the Applicants requested that Claims 21 and 22 be canceled. The Restriction was made final with the issuance of the Advisory Action on November 21, 2006. Hence, it is noted that the Applicants are not contesting the restriction of Claims 21 and 22, which should be canceled. However, for the reasons stated herein below, the Applicants maintain the traversal of the restriction with respect to Claims 15 – 20, and request reconsideration.

The Applicants respectfully submit that the withdrawal of Claims 15 to 20 is improper. As set forth in M.P.E.P. § 806, "where inventions are related as disclosed but are not distinct as claimed, restriction is never proper." Accordingly, the Applicants contend that the Claims 15 to 20 are not directed to an invention that is distinct from the invention of Claim 1 and thus are not properly restricted therefrom.

Specifically, Claims 15-17 recite the use of a second therapy in addition to the therapy set forth in Claim 1. Applicants respectfully submit that the combination of a second therapy with the methods set forth in Claim 1 provide for an alternative embodiment of the main invention, and do not constitute

an independent and distinct invention. Additionally, these alternative embodiments do not constitute an unreasonable burden to search, as the embodiments are closely related.

Claims 18-19 are NOT drawn to the use of a second therapy for psoriasis. The claims merely provide alternative routes of administration for the claimed therapy, where one may select dermal administration or systemic administration. Applicants respectfully submit these alternative embodiments do not constitute an unreasonable burden to search, as the embodiments are closely related. 35 U.S.C. §§ 121, 1.141 and 1.142 all require that, for an application to be restricted, the alleged different inventions must be both independent **and** distinct. Applicants do not believe that a method of systemic administration of an ILK inhibitor, for example, is an independent and distinct invention from the base claim that recites the use of such an inhibitor without specifying the route of administration.

Claim 20 recites the same method of treatment as Claim 1, i.e., administering an effective amount of an inhibitor of integrin linked kinase (ILK), wherein said ILK inhibitor is a small organic molecule that inhibits ILK activity. The essential feature of the claimed invention, which is a treatment of psoriasis with an effective amount of an ILK inhibitor, is the same in both Claim 1 and Claim 20. The difference between these claims is that Claim 20 specifically recites a step for determining whether expression of ILK in psoriatic tissue correlates with severity of disease. As such, Claim 20 is properly considered as an alternative embodiment within the genus of Claim 1, and is not an independent and distinct invention.

Therefore, in view of the above, the Applicants respectfully request a review of the Restriction Requirement and rejoinder of Claims 15 – 20.

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The Commissioner is hereby authorized to charge any other fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815, order number KINE-001CIP5.

Respectfully submitted,

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Date: Dec. 21, 2006

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